ATTACHMENT 13

510(k) Summary

As Required by 21 section 807.92 (c) K083756

1-Submitter Name: SelectiveMed™ Components, Inc
2-Address: 564 Harcourt Road
Mount Vernon, OH 43050
3-Phone: 740 397 7838
4-Fax: 740 397 6112
5-Contact Person: Mr Rick Fisher (President)
6-Date summary prepared: June 11th, 2009

JUN 26 2009

7- Official Correspondent: Mansour Consulting LLC
8- Address: 845 Aronson Lake Court. Roswell, GA 30075 USA
9- Phone: 678-908-8180
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President

12-Device Trade or Proprietary Name: Guardian 150 electrode.
Model Numbers 150, 151, 152 and 3637

13-Device Common or usual name: Electrode for TENS, TENS/NMES including for muscles necessary for pharyngeal contraction

14-Device Classification Name: Electrode, cutaneous

15-Substantial Equivalency is claimed against

The electrode of the Chattanooga VitalStim, cleared under K023347 (Chattanooga group)
Guardian disposable TENS and TENS/NMES electrodes cleared under K945676 (SelectiveMed™ Components, Inc)
Columbia 600 Electrode cleared under K080386 (Columbia Scientific Development, LLC)

16-Description of the Device:

Guardian 150 electrode is a single-patient, single use, self-adhering electrode for use with TENS and NMES, and available in cloth (models 150, 151, 152 and 3637), pre-wired (model 3637), snap (models 150, 151 and 152) and pin style (model 3637) configurations. It is latex-free.

17-Intended use of the device: (refer to FDA form attached)

Guardian 150 electrode is intended for use with TENS and NMES, including for Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

18-Safety and Effectiveness of the device:

Guardian 150 electrode is safe and effective as the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

SelectiveMed Components, Inc.
% Mansour Consulting Inc.
Mr. Jay Mansour
President
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K083756
Trade/Device Name: Guardian 150 electrode- Models 150, 151, 152 and 3637
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: June 11, 2009
Received: June 17, 2009

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 14

Indications for Use

510(k) Number (if known):

Device Name: Guardian 150 electrode- Models 150, 151, 152 and 3637

Indications For Use:

Guardian 150 electrode is indicated for use with TENS and NMES, including for Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083756